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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
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Subject:	**PREPARATION FOR THE COUNCIL (ENVIRONMENT) ON 17 DECEMBER 2024** Proposal for a Regulation of the European Parliament and of the Council on preventing plastic pellet losses to reduce microplastic pollution - General approach

I. INTRODUCTION

1. On 16 October 2023, the Commission put forward a proposal for a Regulation on preventing plastic pellet losses to reduce microplastic pollution[1]. This proposal sets requirements for the handling of plastic pellets by economic operators and EU and non-EU carriers at all stages of the supply chain. Losses of plastic pellets, one of the main sources of unintentional microplastic pollution, often result from a lack of awareness or poor handling practices and can be abated by swift measures. However, once lost in the environment, plastic pellets are nearly impossible to retrieve as they disperse easily over large distances by wind and water.

2. The Economic and Social Committee adopted its opinion on the proposal on 14 February 2024. The Committee of the Regions adopted its opinion on the proposal on 18 April 2024.

3. The European Parliament adopted its position at first reading on 23 April 2024[2] in the previous legislative term under the rapporteurship of João Albuquerque (S&D). In the new legislative term of the EP, César Luena (S&D) has been appointed Rapporteur.

II. WORK IN THE COUNCIL

4. Within the Council, the Working Party on the Environment (WPE) is responsible for examining the proposal at technical level. The Commission presented its legislative proposal and the accompanying impact assessment to the WPE on 14 February 2024.

5. Under the Belgian Presidency, the Council (Environment) held a policy debate on adequacy of the proposed measures, on responsibility of different actors and on maritime transport[3].

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1 14248/23 + ADD 1.
2 10567/24.
3 7753/24.

6. Building upon the progress made during the Belgian Presidency, the Hungarian Presidency has pursued work at technical level and has put forward compromise texts on the whole of the proposal for discussion at five WPE meetings[4].

7. The Presidency obtained political guidance from Coreper on 6 November 2024 with respect to three sensitive issues: (i) the inclusion of maritime transport in the scope of this Regulation, (ii) the treatment of non-EU carriers in relation to obligations put on EU carriers, and (iii) the differentiated obligations for economic operators, based on their size and the volume of pellets handled.

8. Following the guidance received from Coreper, the Presidency has further adjusted the text with additional input from delegations during two additional WPE meetings. In addition to the issues discussed in Coreper, the Presidency provided the delegations with an opportunity to express their preference on permits and certificates for economic operators, definitions, reduction of administrative burden and other points. Based on those discussions, the Presidency has introduced a small number of technical adjustments to the text.

9. As a result, the Presidency puts forward a revised compromise text for a General Approach. This comprehensive text sets a balance between introducing ambitious and effective measures to minimise microplastic pollution caused by plastic pellet losses and providing flexibility for Member States in implementation of the Regulation without placing disproportionate administrative burden on competent authorities and economic actors.

10. The Presidency aims to reach an agreement on a General Approach on the Plastic pellets proposal at the Environment Council on 17 December 2024.

[4] 12265/24; 12265/1/24 REV 1; 14529/1/24 REV 1; 15260/24; and 15908/24.

III. MAIN ELEMENTS OF THE PRESIDENCY COMPROMISE TEXT

General provisions (Articles 1 and 2)

Scope

11. In Article 1, the Presidency maintains the aim of the Regulation, setting out obligations for the handling of plastic pellets along the supply chain. Specifying the supply chain stages, the Presidency includes recycling in the context of production from recycled plastics, as opposed to recycling in the context of waste treatment which is covered in other EU legislative acts.

12. The subjects covered by the Regulation are expanded to better target cleaning installations and, most notably, to include actors involved maritime transport of plastic pellets. Specifically, shippers, operators, agents and masters of sea-going vessels are concerned when leaving or calling at a port of a Member State.

Definitions

13. In Article 2, the compromise text introduces a number of modifications to the definitions included in the Commission proposal as well as a number of new definitions reflecting broader changes by the Presidency. Most notably, these include:

- Clarifying the 'plastic pellets' definition;
- Introducing the definitions of 'shipper', 'operator', and 'agent' in line with the inclusion of maritime transport in the scope of this Regulation;
- Adding the 'authorised representative' definition reflecting the newly introduced approach to ensure a level playing field between EU and non-EU carriers; and
- Including the definition of 'permit' concerning the added flexibility to rely on a permitting system as an alternative to certification.

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Maritime transport (Article 4a)

14. The Commission proposal does not address maritime transport of plastic pellets. Reflecting the significant risk to the environment caused by losses of plastic pellets when transported by sea, the Presidency includes sea-going vessels in the scope of the Regulation. Maritime transport accounted for around 38% of all pellets transported to and within the EU in 2022. The text, however, recognises that maritime transport has global implications and is primarily addressed in the International Maritime Organisation (IMO). Therefore, the Presidency text adopts the IMO's recommendations as mandatory obligations for sea-going vessels in the context of this Regulation to complement the overall IMO and EU legal framework on the safety of maritime transport and the prevention of pollution from sea-going vessels.

15. Specifically, with detailed reasoning in a new recital 14a, the Presidency adds new obligations regarding the transport of plastic pellets by sea in freight containers in Article 4a.

Obligations for economic operators (Articles 3, 4, 5 and 6 and Annexes I, II and IV)

General obligations

16. With the goal of reducing the risk of pellet losses, the Presidency compromise text maintains the obligations for all economic operators handling more than five tonnes of plastic pellets annually, requiring them to avoid and clean up potential losses, notify competent authorities about installations handling pellets and their changes in those installations, as well as to develop a comprehensive risk management plan.

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17. The Presidency compromise text follows the Commission proposal in maintaining additional obligations for economic operators that are medium- and large-sized enterprises handling more than 1000 tonnes of pellets annually. Such obligations include carrying out an internal assessment and obtaining a certificate from certifiers in accordance with Article 5, as opposed to a self-declaration of conformity renewed every five years reserved for operators handling less than 1000 tonnes of pellets annually.

18. In order to increase the environmental protection as requested by delegations, the Presidency compromise text diverges from the Commission proposal by imposing additional obligations to carry out an internal assessment and to obtain a certificate also on small-sized enterprises handling more than 1000 tonnes of pellets annually.

19. However, to avoid disproportionate burden on small-sized enterprises, the Presidency text provides them with an extra implementation period of 48 months and sets the frequency of certificate renewal at five years, compared to three years for large-sized and four years for medium-sized enterprises. Furthermore, small-sized enterprises handling more than 1000 tonnes of pellets annually are not required to follow Annex I, point 9, which lays down additional actions to be taken by medium- and large-sized operators handling more than 1000 tonnes of pellets annually.

Permitting, certification and environmental management systems

20. To provide Member States with additional flexibility with ensuring compliance of economic operators, the Presidency compromise text includes a new Article 5a allowing Member States to rely on already existing national permitting systems. This flexibility complements the compliance assurance through certificates issues by certifiers, in accordance with Article 5. The compromise text ensures that the conditions required by permits mirror those required by certificates.

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21. In Article 6, the Presidency introduces an additional flexibility for Member States to exempt economic operators from certain obligations when the operators prepare and implement an environmental management system (EMS). This is an addition to the exemption through the Community eco-management and audit scheme (EMAS), included in the Commission proposal.

Obligations for carriers (Articles 3, 3a, 4 and Annex III)

General obligations

22. Carriers, both EU and non-EU, are required to comply with a set of obligations under Articles 3 and 5 to prevent plastic pellet spills and losses to the environment. Obligations specific for carriers are laid down in Article 4 and Annex III and include a notification of their activity to competent authorities, ensuring their staff is trained, keeping records of actions related to their obligations and of estimated quantities of pellets handled and of losses. Annex III sets out measures for prevention, for containment and clean-up as well as the equipment that carriers are required to have on board when transporting pellets.

Authorised representative

23. Reflecting the necessity to establish a level playing field between EU and non-EU carriers, the Presidency text extends the obligations that were originally intended solely for EU carriers to non-EU carriers as well. Whilst this is instrumental to achieve an overall reduction of pellet losses risks in transport, the enforceability of several obligations in non-EU carriers became difficult. Therefore, the Presidency text introduces, in new Article 3a, the obligation for non-EU carriers to mandate an authorised representative, allowing Member States to ensure compliance in both EU and non-EU carriers, and thus ensuring a level playing field.

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Other issues

Public access to information

24. In new Article 7a, the Presidency text stipulates that competent authorities make available to the public certain information reported to them by economic operators, carriers and authorised representatives. Following requests by delegations, public access to information is subject to business confidentiality as well as the safety of installations, populations and other interests concerned.

Penalties and compensations

25. The Presidency text aligns Article 15 on penalties with the revised Industrial Emissions Directive, notably highlighting administrative financial penalties, lowering the maximum level of penalties to at least 3 % of the annual Union turnover of the operator, and introducing the flexibility for Member States to use criminal penalties.

26. Similarly, in Article 16 on compensations, the Presidency removes provisions concerning collective action and the reversal of the burden of proof. Further, the provision on statutory limitation period is made voluntary.

Delegated powers

27. In Article 17, the empowerment of the Commission to amend Annexes is made more specific to clarify the delegation of powers and its basis.

Review

28. To ensure effective implementation of the Regulation, the Presidency introduces new provisions on evaluation and review in Article 18b, to be conducted within five years from the application date of the Regulation. The proposed report will include, among others, as assessment of the need to establish a threshold on the quantities of plastic pellets transported by carriers, and of the functioning of authorised representatives.

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IV. CONCLUSION

29. The Presidency compromise text for a General Approach is set out in the Annex to this note. Changes to the Commission's proposal are marked in **bold** and deletions by **[…]**.

30. Against this background, the Permanent Representatives Committee is invited to:

- examine the text in the Annex, and
- forward it to the Council (Environment) with a view to reach agreement on a General Approach at its meeting on 17 December 2024.

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ANNEX

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on preventing plastic pellet losses to reduce microplastic pollution

PUBLIC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure[3],

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1 **[…] OJ C , C/2024/2487, 23.4.2024, ELI: http://data.europa.eu/eli/C/2024/2487/oj.**

2 **[…] OJ C , C/2024/3675, 26.6.2024, ELI: http://data.europa.eu/eli/C/2024/3675/oj.**

3 **Position of the European Parliament of … and decision of the Council of …**

Whereas:

(1) Microplastics are ubiquitous, persistent and transboundary. They are detrimental to the environment and potentially harmful to human health. Microplastics are easily transported through the air and by land surface waters and ocean currents, and their mobility is an aggravating factor. They are found in soil (including agricultural lands), lakes, rivers, estuaries, beaches, lagoons, seas, oceans and in remote, once pristine regions, and their presence in soil **[…] has** effects on soil properties and trigger soil alterations which negatively impact the growth of some plants. Impacts of microplastics on the marine environment have been extensively documented. Once in the marine environment, microplastics are nearly impossible to collect, and are known to be eaten by a range of organisms and animals and cause harm to biodiversity and ecosystems. The persistence of ~~a~~ plastic pellet**s** in the aquatic environment **[…] can** be measured over decades or more, and ingestion of plastic pellets by marine wildlife, notably seabirds and sea turtles, may cause physical harm or death. Microplastics also contribute to climate change as an additional source both of greenhouse gas emissions and of pressure on ecosystems. Microplastics' potential to act as a carrier for adsorbed toxicants or pathogenic microorganisms is an integral part of the problem. Humans are exposed to microplastics via air and food consumption. The growing awareness of microplastics' presence in the food chain can undermine consumer confidence and bear economic consequences. There may be negative economic impacts on activities such as commercial fishing and agriculture as well as recreation and tourism in areas affected by the releases.

(2) In their opinion **of 30 April 2019** entitled 'Environmental and health risks of microplastic pollution', the Commission's Group of Chief Scientific Advisors considered that 'there are significant grounds for concern and for precautionary measures to be taken'.

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(2a) Plastic pellet refers to every small polymer-containing moulding materials, from primary and secondary origin, regardless of whether they are derived from biomass or intended to biodegrade over time, including polymer-based rubber. It encompasses materials used in product manufacturing operations, regardless of its shape or form, including, among others, plastic nurdles, granules, flakes, resins, cylinders, beads, powder, micro-powder, microspheres and agglomerates.

(3) Plastic pellet losses constitute the third largest source of microplastics unintentionally released to the environment in the Union and **[…] occur** due to poor handling practices at all stages of the **plastic pellet** supply chain, **which includes production including […] recycling, master batching, compounding, conversion, processing, distribution, transport, including by the sea, and other logistic operations, storage, packaging , and the cleaning of plastic pellet containers and tanks**. Hence, a supply chain approach is essential for ensuring the commitment of all economic actors involved in plastic pellet handling towards loss prevention. Since 2015, the European plastic manufacturing industry has progressively adopted the international Operation Clean Sweep® **(OCS) programme […]** as a voluntary pledge. Under this programme, each company making or handling pellets recognises the importance of making zero pellet losses and commits to adopting best practices. While such practices are generally well understood by OCS signatories, they have not been comprehensively implemented. The uptake of **[…] that** programme by the plastic industry remains low.

(4) The impacts of microplastic pollution on the environment and **[…]** on human health have raised concerns in most parts of the world. Some Member States have adopted or proposed dedicated measures. However, a patchwork of national restrictions could potentially hamper the functioning of the internal market.

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(5) In a bid to tackle plastic pollution, **[…]** the Commission **[…] has in its communication of 16 January 2018** entitled 'European Strategy for Plastics' **in a Circular Economy** acknowledged the risks posed by microplastics and called for innovative solutions targeting the different sources of microplastics to be taken. **[…] The Commission renewed […] that in its communications of 11 December 2019 on** the European Green Deal **[…], of 11 March 2020 on** the new Circular Economy Action Plan[…] **[…]** and **on** the Zero Pollution Action Plan[…] **[…]**. The latter includes, among its 2030 targets, reducing the amount of microplastics released into the environment by 30%.

(6) Commission Regulation (EU) 2023/2055[6] addresses microplastic pollution by imposing a restriction on the placing on the market of microplastics that are intentionally added to products **[…]**, as there is considerable microplastic pollution arising from the use of synthetic polymer microparticles on their own or intentionally present in products, and pollution poses an unacceptable risk to the environment.

(7) In 2021, the **contracting** parties to the Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR **Convention**) adopted the non-binding Recommendation 2021/06[…] to reduce the loss of plastic pellets into the marine environment by promoting the timely development and implementation of effective and consistent pellet loss prevention standards and certification schemes for the entire plastic supply chain. Measures for minimizing the risk associated with the transport of plastic pellets by sea are under examination at the International Maritime Organization **(IMO) which approved the non-binding circular MEPC.1/Circ 909 on recommendations for the carriage of plastic pellets by sea in freight containers. In this context, the Union and its Member States should follow closely any future developments at the IMO, and play a leading role in ensuring a high-level of environmental protection on this issue, among others by setting a high standard of protection.**

[…] **[…]**

[…] **[…]**

6 Commission Regulation (EU) 2023/2055 of 25 September 2023 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards synthetic polymer microparticles (OJ L 238, 27.9.2023, p. 67).

[…] **[…]**

(8) In the Union submission to United Nations Environment Programme in view of the second session of the Intergovernmental Negotiating Committee on an international legally binding instrument on plastic pollution (INC-2)[…], the Union and its Member States stressed the need for the future instrument to include measures to reduce unintentional releases of microplastics.

(9) Despite Union **[…] legal acts** concerning the prevention of waste, pollution, marine litter and chemicals, there are no specific Union rules preventing pellet losses as a source of microplastic pollution along the entire supply chain. Directive 2008/98/EC of the European Parliament and of the Council[9] lays down basic waste management principles and imposes general obligations for Member States to take measures to prevent waste generation. Those general obligations should be complemented by addressing specific aspects and requirements for the careful handling of plastic pellets in order to avoid them becoming waste.

(10) While the production of polymeric materials on an industrial scale fall under the scope of Directive 2010/75/EU of the European Parliament and of the Council[10], other activities like the conversion, transport or storage of pellets, usually operated by small and medium-sized enterprises, are not covered by that Directive. Moreover, the Reference Document on Best Available Techniques in the Production of Polymers of August 2007[…], established pursuant Council Directive 96/61/EC[12] concerning integrated pollution prevention and control, does not address the specific issue of pellet losses.

[…] **[…]**

9 Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3).

10 Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p.17).

[…] **[…]**

12 Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control (OJ L 257, 10.10.1996, p. 26).

(11) Directive 2008/56/EC of the European Parliament and of the Council[13] addresses the monitoring and assessment of the impacts of microlitter, including microplastics, in coastal and marine environments. An update of the first guidance on monitoring marine litter is under development in view of harmonised methodologies including to monitor the presence and distribution of plastic pellets along the coastline. However, Directive 2008/56/EC does not include specific requirements concerning the prevention or reduction of pellet losses at source.

(12) Commission Regulation (EU) 2023/2055 addresses losses of synthetic polymer microparticles for use at industrial sites i.e. plastic pellets as avoidable releases. For these releases, a reporting requirement for an estimated quantity of microplastics released to the environment on an annual basis is introduced. While lacking a methodology to estimate losses, this requirement will increase information on pellet losses and improve the quality of the information collected to assess the risks deriving from these microplastics in the future.

(13) To ensure that plastic pellets are handled safely and responsibly at all stages of the **plastic pellet** supply chain, so that losses to the environment are prevented, it is necessary to establish requirements on the handling of plastic pellets along the entire supply chain**, namely in**: production, **including output from recycling,** master batching **[…],** compounding, conversion, **[…]processing,** distribution, **[…]**transport, storage**, packaging,** and tank **and container** cleaning at cleaning stations.

(14) Such requirements should take into account internationally recommended good handling practices as well as existing requirements on the handling of plastic pellets established by the industry in the Union. **In this regard, the European Union and its Member States may pursue efforts to make the recommendation in MEPC. 1/Circ 909 mandatory at international level. Furthermore, the Union may promote discussion at international level on the obligation for carriers to notify competent authorities when transporting plastic pellets in a country different from the one in which they are established.**

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[13] Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p.19).

(14a) If plastic pellets are released and dispersed into the marine environment, they can harm living resources and marine life and can interfere with other legitimate uses of the sea, such as fishing and aquaculture. As plastic pellets look like fish egg to birds, despite the fact that only 0.05% of plastic pieces from surface waters are pellets, they comprise about 70% of the plastic eaten by seabirds. These small plastic particles have been found in the stomachs of 63 of the world's approximately 250 species of seabirds.

Furthermore, by weight, plastic pellets are estimated to be the second largest direct source of microplastic marine pollution; it is estimated that billions of individual pellets enter the ocean every year. This is due to both small and large-scale losses and spillages occurring on land and sea during all stages of the supply chain, especially while they are in transit.

Additionally, the pellets can be washed up on beaches and coastlines and, as a result, negatively impact tourism and shore-based activities. Several incidents involving seagoing vessels resulted in several tonnes of plastic pellets being released in the marine environment with disastrous consequences for the environment and local communities. For example, the Toconao accident impacting the northern coast of Spain in 2023 causes the loss of six containers, amongst which one container holding one thousand 25kg sacks of pellets. This resulted in millions of pellets arriving on the Galician Coast.

To address this issue from the perspective of maritime transport, the IMO Marine Environment Protection Committee approved in 2024 MEPC.1/Circ.909 providing recommendations for the carriage of plastic pellets by sea in freight containers. However, since those recommendations are not legally binding, the Union, in line with its obligation under the Treaties to preserve, protect and improve the quality of the environment, and to promote measures at international level to deal worldwide environmental problems, has adopted requirements which are legally binding on certain operators of seagoing vessels to pioneer worldwide a higher level of environmental protection in this field.

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These requirements complement the overall IMO and EU legal framework on the safety of maritime transport and the prevention of pollution from ships, notably Directive 2002/59 which established a system to prevent accidents and pollution at sea taking into account the international legal rules.

(15) Economic operators, EU carriers and non-EU carriers should implement the requirements on the handling of plastic pellets by following a priority order of action **[…] for** preventing the release of pellets in the environment as the top priority. Therefore, preventing spills of plastic pellets from primary containment during routine handling, thus reducing the risk of spills to the lowest possible level, should be the first step, including by avoiding any unnecessary handling (for instance by reducing the transfer points) and by using **[…] good quality** packaging, followed by containment of spilled pellets to make sure they do not become a loss to the environment, and eventually by clean up after a spill or loss event as the final step.

(16) While the aim is to prevent plastic pellet losses to the environment for all economic operators, EU carriers and non-EU carriers, obligations for micro-, small and medium-sized enterprises should be adjusted to mitigate the burden on them.

(16a) Member States, on the other hand, should not be prevented from introducing or maintaining more stringent protective measures. Such measures, including targeting economic operators handling more than 5 tonnes of plastic pellets, are to be compatible with the Treaties.

(17) The registration of installations handling plastic pellets and of carriers transporting them is necessary for the traceability of plastic pellets handled and transported in each Member State and to allow competent authorities to perform compliance checks efficiently.

(18) In order to prevent plastic pellet losses, economic operators should establish, implement, and update at all times a risk **management plan, including a risk assessment […],** identifying potential for spills and losses and documenting in particular **existing** specific equipment and procedures in place to prevent, contain and clean up pellet losses. **The risk management plan should also consider the costs and benefits of additional equipment and procedures to address the identified risks** taking into consideration the installation size and the scale of operations.

(19) To enable competent authorities to verify compliance with the risk **[…] management** plan's requirements, economic operators should provide the competent authority with the risk **[…] management** plan they have **[…] developed**, together with a self-declaration of conformity **or a certificate, as applicable**.

(20) Economic operators should be able to **[…] determine through a risk-based approach** the specific equipment to install or the procedure**s** to **[…] implement**. Nevertheless, competent authorities, while verifying compliance, should be able to require economic operators to amend the risk **[…] management** plan including by taking, in a given timeframe, any of the actions listed in this Regulation to ensure adequate implementation of the requirements of this Regulation.

(21) In order to evaluate the adequacy of the risk **[…] management** plan **[…] designed** for each installation, economic operators should keep record of an estimate of the quantity of the pellets released to the environment per year, together with the total **[…] quantities** handled. To reduce burden on economic operators, the **competent authorities and certifiers should be able to use** information on estimates of quantities released **[…]** in the framework of the reporting requirement under Commission Regulation (EU) 2023/2055.

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(22) Due to the characteristics of their activity, carriers should not be mandated to **[…] develop and implement** a risk **[…] management** plan. Instead, they should be required to undertake tangible measures aimed at preventing, containing, and addressing spills and losses. These measures should be subject to verification by competent authorities, primarily during the transportation process.

(22a) Non-EU carriers should designate an authorised representative, which should act on behalf of the non-EU carrier and may be addressed by any competent authority. The representative should be explicitly designated by a written mandate of the non-EU carrier with regard to specific obligations under this Regulation. The designation of such representative does not affect the responsibility or liability of the non-EU carrier under this Regulation. The authorised representative should be subject to enforcement proceedings, as far as its mandate is concerned, in the event of non-compliance by the non-EU carrier.

(23) The successful implementation of the actions required to prevent plastic pellet losses requires the full cooperation and commitment of economic operators', EU carriers' and non-EU carriers' employees. Economic operators**, […]** EU carriers **and non-EU carriers** should be required to train their staff according to their employees' specific roles and responsibilities in order to ensure they are aware of and are able to use the equipment and execute the procedures necessary to ensure compliance with the requirements laid down in this Regulation. Economic operators**,** EU carriers **and non-EU carriers** should also be required to monitor and keep records of the relevant actions to implement the requirements set out in this Regulation, for instance, the placement of new catchment devices. Where appropriate, they should adopt corrective actions including, where necessary, the improvement of equipment and procedures in place.

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(24) **[…] Economic operators that are not micro** enterprises **and** that operate installations where plastic pellets are handled in quantities **equal to or** above **the threshold of** 1 000 tonnes may bring higher risks of pellet losses to the environment. For this reason, these enterprises should be required to implement, for each installation, extra actions like carrying out an annual internal assessment, and **in case of medium and large-sized enterprises,** adopting a training programme addressing specific training needs and modalities. **The internal assessment can among others cover the following subjects: the estimated quantities and causes of losses; the preventive, containment and clean up equipment or procedures implemented to avoid future losses, and their effectiveness; discussions with the personnel, inspections of equipment and procedures in place and revision of any relevant documentation.** In addition, for these enterprises, compliance with the requirements laid down in this Regulation should be demonstrated by obtaining, and renewing, a certificate issued by certifiers. **The certifier, in particular consultancy services, should not engage in any activity that may conflict with their independence of judgement, or integrity in relation to the certification activities for which they are accredited.** These certifiers can either be an accredited conformity assessment body, or an environmental verifier licenced to carry out verification and validation in accordance with Regulation (EC) No 1221/2009 of the European Parliament and of the Council[14] on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS)**, or an environmental verifier licenced to carry out verification and validation of another environmental management system (EMS).** The certificate should correspond to a unique format in order to ensure homogeneous information.

[14] Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC (OJ L 342, 22.12.2009, p. 1).

(25) Micro **[…]** enterprises~~,~~ and **small,** medium and large-sized enterprises operating installations where plastic pellets in quantities below **the threshold of** 1 000 tonnes have been handled should be required to be subject to a self-declaration of conformity. They should also be given sufficient time to demonstrate their compliance.

(26) To enable competent authorities to more efficiently verify compliance under this Regulation, certifiers should notify competent authorities about the outcome of their assessments. Certificates should not prejudge the assessment on compliance by competent authorities.

(26a) In order to ensure transparency, competent authorities should make certain information publicly available. This includes the notification on installations operated, involvement in the transport of plastic pellets in the Union including significant changes from what was previously notified, the establishment of an authorised representative, risk management plans, self-declarations of conformity, certificates and permits, which should be accessible through an easy-to-find, free, and unrestricted online platform. However, to ensure safety and confidentiality, authorities can withhold specific details if their release would jeopardize the safety of the concerned installations, local populations, or other public interests. The Commission will also publish lists of national websites and authorised representatives of non-EU carriers to ensure wide access to this information while safeguarding business confidentiality.

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(27) In order to be EMAS registered, economic operators are required to comply with environmental legislation, including this Regulation. Consequently, economic operators which are registered to EMAS should be considered compliant with the requirements laid down in this Regulation provided that an environmental verifier has verified that requirements laid down in this Regulation have been included in their environmental management system and implemented. These economic operators should therefore be exempted from the obligations of certification and notification to competent authorities when renewing self-declarations and risk **[…] management plan. In addition to the exemption provided for EMAS and for the purpose of decreasing the burden on other high-integrity systems, it is possible for economic operators that prepare and implement other environmental management systems for each installation to be exempted from compliance in this Regulation upon meeting certain criteria as laid down in this Regulation.**

(28) Competent authorities should verify economic operators', EU carriers' and non-EU carriers' compliance with the obligations arising from this Regulation using, if appropriate, the findings provided as part of the certification or **[…]** self-declarations**. Such verification should be** based**, as appropriate,** on **[…]** environmental inspections or other verification measures, on a risk-based approach. Inspections should, where possible, be coordinated with those required under other Union **[…] legal acts**. Competent authorities should provide the Commission with information on the implementation of this Regulation.

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(28a) Member States may ensure compliance with this Regulation through permits based on a system of regular inspections of installations to examine the full range of relevant environmental effects, including plastic pellet spills and losses. For installations located in a Member State choosing that compliance is to be enforced and verified through such system of permits and regular inspections, economic operators are exempted from obtaining a certificate or submitting a self-declaration of conformity for those installations for which they hold a permit which imposes the conditions necessary for compliance with this Regulation and its Annexes. For installations for which such exemption applies, economic operators should notify the relevant competent authority about the risk management plan and regular updates of the plan. When compliance is ensured through permits, Member States should take the necessary steps to revise the conditions of existing permits and issue new permits such that compliance with this Regulation and its Annexes is ensured in due time.

(28b) According to the Directive 2008/98/EC, Member States should require recyclers to obtain a permit, the conditions of which should ensure that the production of plastic pellets is conducted without endangering human health or harming the environment, particularly avoiding risks to water, air, soil, plants, or animals.

(29) In order to minimise the effects of any loss, the economic operator, EU carrier and non-EU carrier **and shippers, operators, agents and masters of sea-going vessels transporting pellets, where relevant** should take the measures necessary to restore compliance. The corrective action required should be proportionate to the infringement detected and its expected harmful effects on the environment. Where competent authorities detect an infringement of this Regulation, they should notify the economic operator, the EU carrier or the non-EU carrier **and shippers, operators, agents and masters of sea-going vessels transporting pellets, where relevant,** about the infringement detected and require that corrective measures are taken to restore compliance.

PUBLIC

(30) Competent authorities should have a minimum set of inspection and enforcement powers in order to ensure compliance with this Regulation, to cooperate with each other more quickly and more efficiently, and to deter economic operators, EU carriers and non-EU carriers**, authorised representatives, and shippers, operators, agents and masters of sea-going vessels transporting pellets, where relevant,** from infringing this Regulation. Those powers should be sufficient to tackle the enforcement challenges and to prevent non-compliant economic operators from exploiting gaps in the enforcement system by relocating to Member States whose competent authorities are not equipped to tackle unlawful practices.

(31) Competent authorities should be able to use all facts and circumstances of the case as evidence for the purpose of their inspection.

(32) Micro, small and medium-sized enterprises **[…]** in the **plastic** pellet supply chain should comply with the relevant obligations laid down in this Regulation, however they could face proportionally higher costs and difficulties when complying with some of the obligations. The Commission should raise awareness among economic operators and carriers regarding the necessity of preventing pellet losses. Additionally, the Commission should develop training materials to assist them in fulfilling their obligations, particularly with respect to the requirements of the risk assessment. Member States should provide access to information and assistance regarding compliance with obligations and the risk assessment requirements. **[…] The** assistance of Member States **[…] can** include technical and financial support**, as far as necessary and appropriate,** as well as specialised training to **[…].micro, small and medium sized enterprises.** Member States actions should be taken in respect of applicable State aid rules.

PUBLIC

(33) In order to facilitate common grounds to estimate the losses of plastic pellets to the environment, it is necessary to have a standardised methodology set in a harmonised standard that is adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council[15].

[…] Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements set out in this Regulation.

(35) In order to ensure that the objectives of this Regulation are achieved, and the requirements are enforced effectively, Member States should designate their own competent authorities responsible for the application and enforcement of this Regulation. In cases where there is more than one designated competent authority in their territory, in order to ensure effective exercise of the duties of the competent authorities, Member States should ensure close cooperation between all designated competent authorities.

(36) In order to ensure compliance, competent authorities should also take the necessary steps, including inspections and hearings when in possession of and based on relevant information, including substantiated complaints submitted by third parties. Third parties submitting a complaint should be able to demonstrate a sufficient interest **[…]**.

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15 Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12–33*).*

(37) Member States should ensure that any measures taken by their competent authorities under this Regulation are subject to effective judicial remedies in accordance with Article 47 of the Charter of Fundamental Rights of the European Union[…] **(the 'Charter').** According to settled case law of the Court of Justice of the European Union, it is for the courts of the Member States to ensure judicial protection of a person's rights under Union law. Furthermore, Article 19(1) of the Treaty **[…] of the** European Union **(TEU)** requires Member States to provide remedies that are sufficient to ensure effective **[…] legal** protection in the fields covered by Union law. In this respect, Member States should ensure that the public, including natural or legal persons in accordance with this Regulation, has access to justice in line with the obligations that Member States have agreed to as parties to the UN Economic Commission for Europe (UNECE) Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters of 25 June 1998 **[…]**[17] (Aarhus Convention')[…].

(38) In order to ensure **[…]** effective dissua**sion** from non-compliance with the requirements laid down in this Regulation, Member States should lay down rules on penalties applicable to infringements of this Regulation and ensure that those rules are implemented. The penalties provided should be effective, proportionate and dissuasive. To facilitate a more consistent application of penalties, it is necessary to establish common criteria for determining the types and levels of penalties to be imposed in case of infringement. Those criteria should include, inter alia, the nature and gravity of the infringement as well as the economic benefits derived from the infringement in order to ensure that those responsible are deprived of those benefits.

[…] **[…]**

17 **Council Decision 2005/370/EC of 17 February 2005 on the conclusion, on behalf of the European Community, of the Convention on access to information, public participation in decision-making and access to justice in environmental matters (OJ L 124, 17.5.2005, p. 4).**

[…] **[…]**

(39) When setting penalties and measures for infringements, the Member States should foresee that, based on the gravity of the infringement, the level of fines should effectively deprive the non-compliant **[…] persons** from the economic benefit derived from non-compliance with the obligations **[…] under** this Regulation, including in cases of repeated infringements. The gravity of the infringement should be the leading criterion for the measures taken by the enforcement authorities. **[…] For the most serious infringements committed by a legal person, such as those of high level of gravity due to their nature, extent and repetition, of where those infringements pose a significant risk to human health or the environment, t**he maximum amount of fines should represent at least **3** % of the annual **Union** turnover. **For those infringements, without prejudice to the obligations of Member States under Directive 2024/1203/EU[19] of the European Parliament and of the Council, Member States may also or alternatively adopt criminal penalties, provided that they are effective, proportionate and dissuasive.**

(40) Where damage to human health has occurred as a result of an infringement of this Regulation, Member States should ensure that the individuals affected are able to claim and obtain compensation for that damage from the relevant natural or legal persons **[…]** responsible for the infringement. Such rules on compensation contribute to pursuing the objectives of preserving, protecting and improving the quality of the environment and protecting human health as laid down in Article 191 of the Treaty on the Functioning of the European Union **(TFEU).** They also underpin the right to life, integrity of the person and health care laid down in Articles 2, 3 and 35 **[…]** and the right to an effective remedy as laid down in Article 47 of the Charter. Moreover, Directive 2004/35/EC of the European Parliament and of the Council[20] does not give private parties a right of compensation as a consequence of environmental damage or of an imminent threat of such damage.

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19 Directive (EU) 2024/1203 of the European Parliament and of the Council of 11 April 22024 on the protection of the environment through criminal law and replacing Directives 2008/99/EC and 2009/123/EC (OJ L, 2024/1203, 30.4.2024, ELI: http://data.europa.eu/eli/dir/2024/1203/oj).

20 Directive 2004/35/EC of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage (OJ L 143, 30.4.2004, p.56).

(41) To ensure that individuals can defend their rights against damages to health caused by infringements of this Regulation and thereby ensure its more efficient enforcement, non-governmental organisations promoting the protection of human health or the environment, including those promoting the protection of consumers and meeting any requirements under national law, as members of the public concerned, should be empowered to engage in proceedings, as the Member States so determine, either on behalf or in support of any victim, without prejudice to national rules of procedure concerning representation and defence before the courts. Member States usually enjoy procedural autonomy to ensure an effective remedy against violations of Union law, subject to the respect of the principles of equivalence and effectivity. However, experience shows that while there is overwhelming epidemiologic evidence on the negative health impacts of pollution on the population **[…] it is not obvious to link a specific loss of plastic pellets directly to specific impacts on human health or the environment, and such impacts are generally also not immediate.**

(42) In order to take into account technical progress and scientific developments, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission **in respect of amendments to […]** the Annexes **of this Regulation**. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[21]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

[21] OJ L 123, 12.5.2016, p. 1.

(43) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission in respect of reporting of information on the implementation of this Regulation. **Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[22].**

(44) In order to provide economic operators, EU carriers, **[…]** non-EU carriers, **and shippers, operators, agents and or masters of sea-going vessels** with sufficient time to adapt to the requirements laid down in this Regulation, its application should be deferred.

(45) Since the objectives of this Regulation, namely preventing losses of plastic pellets, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale or effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 TEU. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1. This Regulation lays down obligations for the handling of plastic pellets **to prevent losses** at all stages of the supply chain **[…]. That supply chain includes, among others, production including recycling, master batching, compounding, conversion, processing, distribution, transport, storage, packaging and the cleaning of plastic pellet containers and tanks.**

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22 **Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13, ELI: http://data.europa.eu/eli/reg/2011/182/oj).**

2. This Regulation applies to the following subjects:

(a) economic operators handling plastic pellets in the Union in quantities **equal to or** above **a threshold of** 5 tonnes in the previous calendar year;

(aa) economic operators operating installations in the Union for the cleaning of plastic pellet containers and tanks;

(b) EU carriers and non-EU carriers transporting plastic pellets in the Union**;**

(ba) shippers, operators, agents and masters of sea-going vessels transporting plastic pellets in freight containers leaving or calling at a port of a Member State.

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

(a) 'plastic pellet**s**' means a **[…]** mass of **[…]** polymer-containing moulding material, **[…] regardless of its shape, form or size** that is used **[…] in** product manufacturing operations;

(b) 'spill' means a one-off **or prolonged** escape of plastic pellets **within installation's boundaries or within road vehicles, rail wagons, or inland waterway vessels transporting plastic pellets** from primary containment;

(c) 'loss' means a one-off or prolonged escape of plastic pellets from installation's boundary to the environment or from **road vehicles, rail wagons or inland waterway vessels transporting plastic pellets**;

(d) 'installation' means any premises, structure, **[…] location, site** or place within which one or more economic activities involving the handling of plastic pellets are carried out;

(e) 'economic operator' means any natural or legal person who operates or controls in whole or in part the installation, or, where this is provided for in national law, to whom decisive economic power over the technical functioning of the installation has been delegated;

(f) 'EU carrier' means any natural or legal person established in a Member State, engaged in the transport of plastic pellets as part of its economic activity by using road vehicles, rail wagons or inland waterway vessels;

(g) 'non-EU carrier' means any natural or legal person established in a third country, engaged in the transport of plastic pellets as part of its economic activity in the Union by using road vehicles, rail wagons or inland waterway vessels;

(ga) 'shipper' means shipper as defined in Directive 2002/59/EC;

(gb) 'operator' means the owner or manager of a sea-going vessel;

(gc) 'agent' means any person mandated or authorised to supply information on behalf of the operator of the seagoing vessel;

(h) 'micro**-,** small or medium-sized enterprise' means a micro, small or medium-sized enterprise within the meaning of the Annex to Commission Recommendation 2003/361/EC[23];

(i) 'large-sized enterprise' means an enterprise that is not a micro, small or medium-sized enterprise;

(j) 'competent authority' means an authority or a body designated by a Member State to carry out its obligations under this Regulation;

[23] Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

(ja) 'authorised representative' means a natural or legal person established in the Union who has been designated by a written mandate from a non-EU carrier pursuant to Article 3a , to act on its behalf in relation to specific tasks with regard to the obligations under Article 3, paragraphs 2 and 3, Article 4, paragraph 7, Article 7a, paragraph 2 and Article 10 paragraph 1 of this Regulation;

(k) 'certifier' means any of the following:

(i) a conformity assessment body as defined in Article 2**, point** (13)**,** of Regulation (EC) 765/2008 of the European Parliament and of the Council[24] **[…]**;

(ii) an environmental verifier, as defined in Article 2(20) **[…]** of Regulation (EC) No 1221/2009;

(l) 'conformity assessment' means the process demonstrating whether an installation fulfils the applicable rules of this Regulation and of the delegated acts adopted on the basis thereof;

(m) 'permit' means a written authorisation, issued by the relevant competent authority, to operate an installation.

Article 3

General obligations

1. Economic operators, EU carriers and non-EU carriers shall ensure that losses are avoided. Where losses occur, economic operators, EU carriers and non-EU carriers shall take immediate action to **contain and** clean-up those losses.

[24] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

2. Economic operators **[…]** shall notify the competent authori**ties […] of the […] Member State about each installation located in that Member State which** they operate **[…] or control, or, where applicable, have delegated decisive economic power over the technical functioning of the installation. Before carriers transport […] plastic pellets in the Union for the first time, EU carriers and authorised representatives referred to in Article 3a, as applicable, shall notify the competent authorities of the Member State in which […], respectively, the EU carrier or the authorised representative is established, about their involvement in the transport of plastic pellets within the Union..**

3. Economic operators**, […]** EU carriers **and authorised representatives** shall notify the competent authorities **[…] referred to in paragraph 2** of any significant change in **[…] what was previously notified in accordance with paragraph 2 regarding the concerned** installations and activities related to handling **[…] and transporting** plastic pellets, including ~~of~~ any closure of an existing installation**, cessation of transport activities or in case they are no longer subject to this Regulation.**

[…]

Article 3a

Authorised representatives of non-EU carriers

1. Non-EU carriers shall designate in writing an authorised representative in at least one Member State where it is engaged in the transport of plastic pellets.

2. The authorised representative shall be mandated by non-EU carriers in writing to be addressed in addition to or instead of that non-EU carrier, for the purposes of ensuring compliance with Article 3, paragraphs 2 and 3, Article 4, paragraph 7, and Article 7a, paragraph 2 and Article 10 paragraph 1 of this Regulation. The authorised representative's mandate shall be valid only when accepted in writing by the authorised representative. The designation of an authorised representative shall be without prejudice to legal actions which could be initiated against the non-EU carriers themselves.

PUBLIC

3. The non-EU carrier shall inform the competent authorities of the Member State referred to in paragraph 1 and simultaneously the Commission on the designation of an authorised representative and its mandate before the first transport of plastic pellets in the Union.

PUBLIC

Article 4

Obligations regarding the handling of plastic pellets

1. Economic operators shall take the following actions:

   (a) establish a risk **[…] management** plan for each installation in accordance with Annex I taking into account the nature and size of the installation as well as the scale of its operations;

   (b) install the equipment and execute the procedures described in the risk **[…] management** plan referred to in point (a);

   (c) notify the risk **[…] management** plan referred to in point (a) to the competent authority of the Member State where the installation is located together with a self-declaration of conformity issued in accordance with the model form set out in Annex II.

   Economic operators shall keep the risk **[…] management** plan up-to-date, taking into account in particular the weaknesses identified through their experience in handling plastic pellets, and shall make it available to competent authorities on demand.

2. Economic operators that are **small,** medium **[…] or** large-sized enterprises operating installations where plastic pellets in quantities below **a threshold of** 1 000 tonnes have been handled in the previous calendar year or that are micro-**[…]**sized enterprises shall notify an update of the risk **[…] management** plan for each installation as well as a renewal of the self-declaration of conformity to the competent authority every 5 years from the last notification.

3. Competent authorities may require economic operators to take the following actions:

(a) to change risk **[…] management** plans notified in accordance with paragraphs 1 and 2 to ensure that the losses can effectively be prevented or, where appropriate, contained and cleaned up and that Annex I is complied with;

(b) implement any of the actions listed in Annex I in a timely manner.

5. EU carriers and non-EU carriers shall ensure that the actions set out in Annex III are implemented **[…]**.

6. When economic operators implement the actions set out in the risk **[…] management** plan established in accordance with Annex I and the EU carriers and non-EU carriers implement the actions laid down in Annex III, they shall take action, in the following priority order:

(a) actions to prevent spills**;**

(b) actions to contain spills to avoid they become a loss;

(c) actions to clean-up after a spill or loss.

7. Economic operators and EU **and non-EU** carriers shall have the following obligations:

(a) ensure that their staff is trained according to their specific roles and responsibilities and that they are aware of and are able to use the relevant equipment and execute the procedures set out to ensure compliance with this Regulation;

(b) keep records of the actions taken to comply with the obligations set out in this Article;

(c) keep records of annually estimated quantities of losses and of the total **[…] quantities** of plastic pellets handled.

PUBLIC

As from **[…] twelve** months after the publication of the relevant harmonised standard in the *Official Journal of the European Union* or from the date of application of the implementing act referred to in Article 13(2) of this Regulation economic operators **and EU and non-EU carriers** shall estimate the quantities of losses referred to in the first subparagraph, point (c)**,** in accordance with the standardised methodology referred to in Article 13.

[…] Authorised representative shall provide evidence of the compliance by non-EU carriers with the obligation laid down in point (a) and economic operators and EU carriers and authorised representative shall retain records referred to in points (b) and (c) of this paragraph for a period of five years and make them available to competent authorities and, where applicable, to certifiers on demand.

8. Where an action taken for the prevention, containment and clean-up of spills and losses fails, economic operators, **EU** carriers and non-EU carriers shall take corrective actions, as soon as possible.

9. Every year economic operators that are not micro **[…]** enterprises **[…]** that operate installations where plastic pellets in quantities **equal to or** above **a threshold of** 1 000 tonnes have been handled in the previous calendar year shall, for each installation, carry out an internal assessment on the state of compliance of the installation with the requirements of the risk **[…] management** plan laid down in Annex I**[…] or with the […] conditions under which the permit was granted according to Article 5a, paragraph 1, point (a).**

[…]

[…]

[…]

PUBLIC

Article 4a

Obligations regarding the transport of plastic pellets by sea in freight containers

1. Shippers shall ensure that:

(a) plastic pellets are packed in good quality packaging that is strong enough to withstand the shocks and loadings normally encountered during transport and is constructed and closed so as to prevent any loss of contents which may be caused under normal conditions of transport, by vibration or acceleration forces;

(b) transport information identifying the freight containers containing plastic pellets is delivered to the operator, agent and master of the sea-going vessel as an addition to the cargo information required by Regulation VI/2 of the International Convention for the Safety of Life at Sea, before plastic pellets are taken on board;

(c) cargo information referred to in point (b) is accompanied by a special stowage request requiring stowage of the freight containers containing plastic pellets as outlined in paragraph 2, point (b) of this Article.

2. Operators, agents and masters of sea-going vessels shall ensure that they are in possession of the list or manifest or appropriate loading plan in accordance with the cargo information received from the shipper referred to in paragraph 1, point (b) of this Article.

3. Operators and masters of sea-going vessels shall ensure that freight containers containing plastic pellets are stowed under deck wherever reasonably practicable, or inboard in sheltered areas of exposed decks. In both cases, such containers are secured to minimize hazards to the marine environment without impairing the safety of the seagoing vessel and persons on board.

PUBLIC

Article 5

Certification

1. By … [**[…]** *24 months* **[…]** ***from*** *the entry into force of this Regulation*], and thereafter every three years, economic operators that are large-sized enterprises shall demonstrate that **the handling process at** each installation where plastic pellets in quantities **equal to or** above **a threshold of** 1 000 tonnes have been handled in the previous calendar year is compliant with the requirements set out in Annex I, by obtaining a certificate issued by a certifier.

2. By … [**[…]** *36 months* **[…]** ***from*** *the entry into force of this Regulation*], and thereafter every four years, economic operators that are medium-sized enterprises shall demonstrate that **the handling process at** each installation where plastic pellets in quantities **equal to or** above **a threshold of** 1 000 tonnes have been handled in the previous calendar year is compliant with the requirements set out in Annex I, by obtaining a certificate issued by a certifier.

2a. By … [*48 months from the entry into force of this Regulation*], and thereafter every five years, economic operators that are small-sized enterprises shall demonstrate that the handling process at each installation where plastic pellets in quantities equal to or above a threshold of 1 000 tonnes have been handled in the previous calendar year is compliant with the requirements set out in Annex I, by obtaining a certificate issued by a certifier.

3. Certifiers shall carry out spot-checks to ensure that **the risk management plan is adequate to prevent plastic pellet losses and that** all measures included in the risk **[…] management** plan carried out in accordance with Annex I are duly implemented.

4. Certificates shall meet the following requirements:

   (a) be issued in accordance with the model form set out in Annex IV and in electronic form;

   (b) specify the economic operator, the installation covered by the certificate, the date of the spot-checks carried out, and the period of validity;

   (c) certify conformity of the installation covered by the certificate with the requirements laid down in Annex I;

PUBLIC

5. Without undue delay, certifiers shall notify the competent authority of the following:

(a) certificates issued;

(b) certificates suspended or withdrawn;

(c) changes in certificates.

[…]

PUBLIC

Article 5a

Compliance through permits

1. Member States may exempt economic operators from the obligations laid out in Article 4(1) (c) and 4(2) as well as from obtaining a certificate according to Article 5(1), (2) and (2a) in respect of each installation, provided that:

(a) the operation of the installation is subject to a permit;

(b) the economic operator has notified the authority competent for the issuance of permits about the risk management plan referred to in Article 4(1) as well as its updates every 3 years for large, 4 years for medium, and 5 years for small and micro-sized enterprises;

(c) the permit has been granted or reviewed and, if necessary, updated based on the verification of the economic operators' compliance with Annex I following the notification of a risk management plan and subsequent updates, done under point (b);

(d) the installation is subject to regular inspections by competent authorities, including spot-checks, with a periodicity equivalent to those indicated in Articles 4(2) and 5 examining the full range of relevant environmental effects, including plastic pellet spills and losses.

2. The Member State shall notify the exemption of the economic operators and national rules on permits to the Commission.

PUBLIC

Article 6

Environmental management systems

1. Economic operators which are registered to the Community eco-management and audit scheme **(EMAS)** in accordance with Regulation (EC) No 1221/2009 are exempt from compliance with the notification obligation laid down in Article 4(2) and the obligations laid down in Article 5(1**), (2)** and (2**a**) of this Regulation provided that the environmental verifier as defined in Article 2(20) of Regulation (EC) No 1221/2009 has checked that requirements laid down in Annex I have been included in the environmental management system of the economic operator and have been implemented.

2. Member States may exempt economic operators from compliance with Articles 4(2), 5(1), 5(2) and 5(2a) of this Regulation when they have prepared and implemented an environmental management system (EMS) for each installation, and provided that:

(a) an accredited certifier has conducted a conformity assessment to verify, including through spot-checks, that the EMS and the way it is implemented are compliant with the requirements set out in Annex I;

(b) the economic operator notifies the competent authorities about the conformity assessment of the EMS and the way it is implemented at the installation with the requirements set out in Annex I, including information about the economic operator, the installation for which compliance is verified, the date at which spot-checks are carried out, and the period for which the conformity assessment is valid;

(c) the regular conformity assessments of the EMS include, at least every three years, an evaluation of its implementation in accordance with Annex I.

Article 7

Accreditation of certifiers

The accreditation of certifiers referred to in Article **[…]2,** point (k)(i)**,** shall include an evaluation of compliance with the following requirements:

(-a) the certifier shall be established under the law of a Member State and shall have legal personality;

(a) the certifier shall be **a third party body** independent of the economic operator;

(b) the certifier, its top-level management and the personnel responsible for the conformity assessment shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to the certification activities **for which they are accredited**;

(c) the certifier and its personnel shall **operate in a non-discriminatory manner and shall** carry out their activities with the highest degree of professional integrity and the requisite technical competence and shall be free from all pressures and inducements, including financial, which might influence their judgement or the results of their certification activities**, especially as regards persons or groups of persons with an interest in the results of those activities. The impartiality of the certifiers, their top-level management and of the personnel responsible for carrying out the certification and tasks shall be guaranteed**;

(d) the certifier shall have the expertise, equipment and infrastructure required to perform the conformity assessment in relation to which it has been accredited;

(e) the certifier shall have a sufficient number of suitably qualified and experienced personnel responsible for carrying out the conformity assessment tasks;

PUBLIC

(f) **without prejudice to the powers of the competent authorities under Article 11(3), point (b),** the personnel of a certifier shall observe professional secrecy with regard to all information obtained in carrying out the conformity assessment tasks;

(g) where a certifier subcontracts specific tasks connected with certification or has recourse to a subsidiary, it shall take full responsibility for the tasks performed by subcontractors or subsidiaries and shall assess and monitor the qualifications of the subcontractor or the subsidiary and the work carried out by them. **Only the tasks that fall in the scope of accreditation of the certifier may be performed by subcontractors or subsidiaries. Certifiers shall ensure that the activities of their subcontractors or subsidiaries do not affect the confidentiality, objectivity or impartiality of their certification activities.**

Article 7a

Public access to information

1. Competent authorities shall make available to the public, including systematically via the internet, on a webpage which is easy to find, free of charge and without restricting access to registered users, while ensuring that confidential business information is safeguarded the following:

(a) the information they have received in accordance with Article 3(2) and (3) and Article 3a;

(b) upon demand, the risk management plans they have received in accordance with Article 4(1);

(c) the self-declaration of conformity they have received in accordance with Article 4(2);

PUBLIC

(d) certificates issued pursuant to Article 5 and notifications they have received in accordance with paragraph 5 of that Article; and

(e) the content of the decision granting a permit, including a copy of the permit and any subsequent updates or a link to other existing publicly accessible registers or websites, established at Member State level, that provide access to such permits and their subsequent updates.

2. Competent authorities, when making them available to the public, may omit parts of the information referred to in paragraph 1, points (a) and (b), if the disclosure of the information would adversely affect the safety of the concerned installations, the local population, or any of the interests listed in Article 4(2), points (a) to (h), of Directive 2003/4/EC. Competent authorities may request economic operators, EU carriers non-EU carriers and authorised representatives to identify the parts of the information that they consider shall not be publicly disclosed.

3. The Commission shall publish the list of such national websites on its website, provided that such information is submitted by Member States.

4. The Commission shall make the list of designated authorised representatives of non-EU carriers pursuant Article 3 available to the public, including systematically via the internet, on a webpage which is easy to find, free of charge and without restricting access to registered users, while ensuring that confidential business information is safeguarded.

PUBLIC

Article 8

Verification of compliance and reporting

1. Competent authorities shall verify compliance of economic operators, EU carriers and non-EU carriers **and authorised representatives, shippers, operators, agents and masters of sea-going vessels transporting plastic pellets in the Union leaving or calling at a port of a Member State** with the obligations laid down in this Regulation, taking into account**, where applicable,** the information provided in self-declarations of conformity referred to Article 4(1) and (2) and **[…] collected** by certifiers in accordance with Article 5(5) **and in accordance with exemptions granted pursuant to Article 6**. The competent authorities shall carry out environmental inspections and other verification measures, following a risk-based approach.

2. At the latest by … [**[…]** *the first day of the month after four years following the date of entry into force of this Regulation*] and every three years thereafter Member States shall, submit a report to the Commission containing qualitative and quantitative information on the implementation of this Regulation during the previous **three consecutive** calendar year**s**. The information shall include:

   (a) the number of economic operators per size of enterprise according to Commission Recommendation 2003/361/EC and per economic activity, their installations, and ~~of~~ the **number of** EU carriers **and non-EU carriers** and their means of transport allocated to transporting plastic pellets;

   (b) the number of risk **[…] management** plans, self-declarations notified pursuant to Article 4(1) and 4(2)**, the number of** certificates notified pursuant to Article 5(5) **and the number of economic operators that are EMAS registered or have implemented an EMS meeting the conditions in Article 6(2)**;

PUBLIC

(ba) the number of permits granted to the exempted economic operators under Article 5a;

(c) the number and results of environmental inspections and other verification measures carried under paragraph 1 of this Article as well as the number of incidents and accidents reported in accordance with Article 9(1) and the measures taken in case of non-compliance with the obligations set out in this Regulation.

3. The Commission shall **[…]** by means of implementing acts **lay down** a format for the reports referred to in paragraph 2. **Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 18a(2).**

Article 9

Incidents and accidents

1. Without prejudice to Directive 2004/35/EC, in the event of an incidental or accidental loss significantly affecting human health or the environment, economic operators, EU carriers and non-EU carriers shall, immediately:

(a) inform the competent authority in whose territory the incident or accident occurred and the estimated quantities of losses;

(b) take measures to limit the health or environmental consequences**;** and

(c) take measures to prevent further incidents or accidents.

2. The competent authority in whose territory the incident or accident occurred shall require, where necessary, that economic operators, EU carriers and non-EU carriers take appropriate complementary measures to limit the health or environmental consequences and to prevent further incidents or accidents.

PUBLIC

3. In the event of any incident or accident significantly affecting human health or the environment in another Member State, the competent authority in whose territory the accident or incident occurred shall immediately inform the competent authority of that other Member State.

Article 10

Non-compliance

1. In the event of an infringement of the rules laid down in this Regulation, economic operators, EU carriers-**[…],** non-EU carriers **and authorised representatives, as applicable,** shall immediately:

   (a) inform the competent authority;

   (b) take the measures necessary to ensure that compliance is restored within the shortest possible time;

   (c) comply with any complementary measures determined by the competent authority as necessary to restore compliance.

2. Where the infringement of the rules laid down in this Regulation poses an immediate danger to human health or threatens to cause an immediate significant adverse effect upon the environment **or leads to a significant loss of plastic pellets**, the competent authority may suspend the operation of the installation **or part of it, immobilise the vehicle or prevent the movement of the transport means** until compliance is restored in accordance with paragraph 1, points (b) and (c).

PUBLIC

Article 11

Designation and powers of competent authorities

1. Member States shall designate one or more competent authorities for the application and enforcement of this Regulation.

2. Member States shall confer on their competent authorities the powers of inspection and enforcement necessary to ensure compliance with this Regulation.

3. The powers referred to in paragraph 2 shall include at least the following:

   (a) the power of access to any relevant documents, data or information related to an infringement of this Regulation, in any form or format and irrespective of their storage medium, or the place where they are stored, and the power to take or obtain copies thereof;

   (b) the power to require any natural or legal person to provide any relevant information, data or documents, in any form or format and irrespective of their storage medium or the place where they are stored, for the purposes of establishing whether an infringement of this Regulation has occurred or is occurring and the details of such infringement;

   (c) the power to start an inspection on their own initiative to bring about the cessation or prohibition of infringements of this Regulation;

   (d) the power of access to installations.

4. Competent authorities may use any information, document, finding, statement or intelligence as evidence for the purpose of their environmental inspections and other verification measures, irrespective of the format or medium on which they are stored.

PUBLIC

5. Where there is more than one competent authority in their territory, Member States shall ensure that appropriate communication and coordination mechanisms are established.

PUBLIC

Article 12

Assistance relating to compliance

1. **By … [*no later than 12 months from the entry into force of this Regulation*],** the Commission shall develop **and make available to the public, including via the internet, on a webpage which is easy to find, free of charge and without restricting access to registered users,** awareness raising and training material on the sound implementation of the obligations laid down in this Regulation in consultation with representatives of economic operators, **EU carriers and non-EU** carriers, **authorised representatives, shippers, operators, agents and masters of sea-going vessels transporting plastic pellets in the Union,** and certifiers, including micro-, small and medium-sized enterprises and in collaboration with competent authorities.

2. Member States shall ensure that economic operators and **EU carriers and non-EU** carriers, **authorised representatives, shippers, operators, agents and masters of sea-going vessels transporting plastic pellets in the Union,** especially micro|-, small and medium-sized enterprises, get access to information and assistance regarding compliance with this Regulation.

   Without prejudice to applicable state aid rules, the assistance referred to in the first subparagraph may take the form of:

   (a) financial support;

   (b) access to finance;

   (c) specialised management and staff training;

   (d) organisational and technical assistance.

3. Member States shall encourage training programmes for the qualification of certifiers' personnel.

PUBLIC

Article 13

[…] Standards

1. For the purposes of compliance with the obligation referred to in Article 4(7), first subparagraph, point (c), a methodology to estimate quantities of losses shall be developed in harmonised standards in accordance with the procedures established by Regulation (EU) No1025/2012.

1a. The Commission shall submit the request for the development of harmonised standards to one or more European standardisation organisations within 12 months after the entry into force of this Regulation.

2. Where no European standardisation organisation accepts the request to draft a harmonised standard or where the Commission considers that the proposed standard does not satisfy the requirements which it aims to cover, the Commission shall establish the methodology referred to in paragraph 1 by means of an **i**mplementing act. **That implementing act shall be adopted in accordance with the examination procedure referred to in Article 18a(3).**

Article 14

Complaint-handling and access to justice

1. Natural or legal persons **[…]**regarded under national law as having a sufficient interest or those who consider that their rights were impaired shall be entitled to submit substantiated complaints to competent authorities when they deem, on the basis of objective circumstances, that an economic operator, EU carrier **[…],** non-EU carrier, **or shipper, an operator, an agent and a master of sea-going vessel** is failing to comply with the provisions of this Regulation.

For the purposes of the first subparagraph, non-governmental entities or organisations promoting **the protection of** human health, environmental~~l~~ or **those promoting** consumer protection and meeting any requirements under national law shall be deemed to have a sufficient interest.

2. Competent authorities shall assess the substantiated complaint referred to in paragraph 1 and, where necessary, take the necessary steps, including inspections and hearings of the person or organisation, with a view to verifying those complaints. If the complaint is found to be grounded, the competent authorities shall take the necessary actions in accordance with Article 4(3).

3. Competent authorities shall, as soon as possible, inform the person or organisation referred to in paragraph 1 that submitted the complaint of its decision to accede to or refuse the request for action put forward in the complaint and shall provide the reasons for it.

4. Member States shall ensure **[…]** a person **[…]** referred to in paragraph 1 **[…]** shall have access to a court or other independent and impartial public body competent to review the procedural and substantive legality of **[…]** the competent authority's decisions, acts or failure to act under this Regulation, **without prejudice to any provisions of national law which require that administrative review procedures be exhausted prior to recourse to judicial proceedings**. Those review procedures shall be fair, equitable, timely and **[…]** not prohibitively expensive, and shall provide adequate and effective remedies, including injunctive relief where necessary.

5. Member States shall ensure that practical information is made available to the public on access to the administrative and judicial review procedures referred to in this Article.

PUBLIC

Article 15

Penalties

1. Without prejudice to the obligations of Member States under Directive **[…] 2024/1203/EU** of the European Parliament and of the Council[…], Member States shall lay down rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are applied. The penalties provided shall be effective, proportionate and dissuasive.

2. The penalties referred to in paragraph 1 shall include **[…] administrative financial penalties that effectively deprive those that** committed the infringement **[…]** of the economic benefits derived from **[…] their** infringements.

   For the most serious infringements […] committed by a legal person, the maximum **[…] level of the administrative financial penalties referred to in the first subparagraph** shall be at least **[…] 3**% of the **[…]** annual **Union** turnover **of the operator** in the **[…] financial** year preceding the **[…] year in which the fine is imposed.**

   Member States may also, or alternatively, use criminal penalties, provided that they are equivalently effective, proportionate and dissuasive to the administrative financial penalties referred to in this Article.

3. Member States shall ensure that the penalties established pursuant to this Article take due account of the following, as applicable:

   (a) the nature, gravity and extent of the infringement;

   […]

   (**[…]b**) the population or the environment affected by the infringement, bearing in mind the impact of the infringement on the objective of achieving a high level of protection of human health and the environment;

[…] **[…]**

([…]c) **[…] repetitive or one-off character** of the **[…] infringement.**

3a. Member States shall without undue delay notify the Commission of the rules and measures referred to in paragraph 1 and of any subsequent amendments affecting them.

PUBLIC

Article 16

Compensation

1. Member States shall ensure that, where damage to human health has occurred as a result of a**n** infringement of this Regulation, the individuals affected have the right to claim and obtain compensation for that damage from the relevant natural or legal persons **[…],** responsible for the infringement.

[…]

[…] 2. Member States shall ensure that national rules and procedures relating to claims for compensation are designed and applied in such a way that they do not render impossible or excessively difficult the exercise of the right to compensation for damage caused by an infringement pursuant to paragraph 1.

[…]

[…] 3. Member States **[…] may establish** limitation periods for bringing claims for compensation referred to in paragraph 1 **[…]**. Such periods shall not begin to run before the infringement has ceased and the person claiming the compensation knows or can reasonably be expected to know that he or she suffered damage from a**n** infringement pursuant to paragraph 1.

Article 17

Amendments to Annexes

The Commission is empowered to adopt delegated acts in accordance with Article **[…]18 to amend:**

[…]

(a) the technical requirements laid down in points (7), (7a), (8) and (8a) of Annex I;

(b) points (1), (2) and (3) of Annex III to add or remove equipment requirements or procedures or to specify the technical features of the existing equipment and procedures; and

(c) the details of the forms laid down in Annexes II and IV

on the basis of:

(a) the experience gained from the implementation of obligations set out in Articles 4 and 5;

(b) relevant international standards **and regulations**;

(c) the specificities of the sectors of activity;

(d) the specific needs of micro**-,** small and medium-sized enterprises**;**

(e) technical progress and scientific developments; and

(f) the experience gained from incidents and accidents.

PUBLIC

Article 18

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 17 shall be conferred on the Commission for a period of **[…] five** years from … [**[…]** *the first day of the month following the date of entry into force of this Regulation*]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 17 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 17 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

PUBLIC

Article 18a

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Article 18b

Evaluation and review

1. Within five years from the date of its application, the Commission shall conduct an evaluation of the implementation of this Regulation in light of the objectives that it pursues. The Commission shall present a report on the main findings of the evaluation to the European Parliament and to the Council. The report shall include:

(a) the experience gathered from the implementation of this Regulation;

(b) the information reported by Member States pursuant to Article 8;

(c) the information made available by economic operators on the reduction of plastic pellet losses resulting from the handling of plastic pellets;

(d) the contribution of this Regulation to the overall target of reducing microplastic pollution by 30 % by 2030;

PUBLIC

(e) an assessment of whether there are additional sources of unintentional releases of plastic pellets or microplastics which are not sufficiently regulated;

(f) the latest data and scientific findings;

(g) the interaction of this Regulation with relevant international initiatives addressing plastic pellet losses, in particular with regards to maritime transport; and

(h) an assessment of the effectiveness of the thresholds on the quantities of plastic pellets handled in accordance with Articles 4 and 5, considering the information reported by Member States pursuant to Article 8, including an evaluation on the impacts of lowering those thresholds;

(i) an assessment of how the exemptions granted under Article 5a impact the effectiveness of this Regulation;

(j) an assessment of the need to establish a threshold on the quantities of plastic pellets transported by carriers;

(k) an assessment of the functioning and responsibilities of authorised representatives established under Article 3a.

2. Where appropriate, the report shall be accompanied by a legislative proposal to the European Parliament and Council.

3. In the event of the adoption by the International Maritime Organisation (IMO) of measures for the safe transport and prevention of marine pollution of plastic pellets by ships, the Commission shall assess these measures, including the need to ensure alignment with those measures, and shall if appropriate, adopt a legislative proposal amending this Regulation accordingly.

PUBLIC

Article 19

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall apply [**[…]** ***24*** *months after the entry into force of this Regulation*]. However, Article 3(1) shall apply from [*OP: please insert the date the date of the entry into force of this Regulation*].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

PUBLIC

ANNEX I

RISK […] MANAGEMENT PLAN FOR INSTALLATIONS

The risk **[…] management** plan referred to in Article 4(1) shall contain the following elements:

(1) the site plan;

(2) the locations where pellet spills and losses may originate from within the installation's boundaries, specifying high- and low-risk locations;

(3) the handling operations during which pellet spills and losses may originate from within the installation's boundaries, specifying high- and low-risk operations;

(4) the estimation of the quantities of spills and losses in the identified locations and operations;

(5) **[…]** the list of the activities **at which plastic pellet spills or losses might occur** over which the installation might have authority to exercise control, including **[…]** suppliers, **(**sub**)-** contractors and off-site storage facilities;

(6) the definition of one specific role of a member of staff responsible for recording, investigating and follow-up on spills and losses, including reporting to competent authorities as in Article 4 (7) and Article 9 (1);

(7) description of equipment **put** in place to prevent, contain and clean up spills and losses**. This equipment shall be adequate and proportionate to the nature and size of the installation and shall include:**

[…]

(a) **For prevention: in case of installations at which packaging takes place, packaging that shall be strong enough to withstand the shocks and loadings normally encountered during transport. The packaging shall be securely constructed and closed so as to prevent any loss of contents which may be caused under normal conditions of transport, by vibration or acceleration forces;**

PUBLIC

(b) **For containment: at high-risk spill locations, catchment devices placed to ensure spills on the floor can easily be contained and cleaned;**

(c) **For clean-up: at spill and loss locations, vacuum cleaners for internal and external usage, sufficient cleaning tools (e.g., brooms, dustpan and brush, buckets, repair tapes) and disposal bins for collected pellets and empty bags;**

(7a) Where appropriate on the basis of the nature and size of the installation as well as the scale of its operations**, economic operators shall consider the description of at least the following additional equipment**:

[…]

(a) For prevention: vacuum seals on hoses and pipework; **in case of installations at which packaging takes place: the strength of the material used and the construction of the packaging is appropriate to the capacity of the packaging and its intended use; the packaging is sift-proof or is provided with a suitable liner; protective covers on forklifts, hydraulic equipment, or other loading and unloading equipment to prevent the piercing of packaging;** equipment to create secure connection points with secondary barriers in place; loading systems designed to ensure transfer lines can be completely emptied after loading and unloading; sealed containers or external silos to store pellets**; […] protection to prevent overfilling of silos; automated transport systems for pellets; plastic pellet dust extraction equipment with appropriate plastic pellet dust filters or catchment devices; for the cleaning of plastic pellet containers or silos, use of filter or catchment devices for rinse water and air cleaning;**

PUBLIC

(b) For containment: **secondary** catchment devices placed **[…] around […] installation;** internal and external drain covers, storm water drainage or filtration systems to manage reasonably foreseeable flood or storm events; a sewage treatment system; **closed containers for spilled pellets and empty packaging; zones to repair or deal with damaged packaging; a floor or underground at loading and unloading areas which does not hinder the cleaning of spills;**

(c) For clean-up: industrial vacuum cleaners **[…];** dedicated **[…]**containers for recovered pellets that are covered, labelled and secured to prevent further spills and losses; **[…]** reinforced collection bags**;**

(8) description of procedures **put** in place to prevent, contain and clean up spills and losses**. These procedures shall be adequate and proportionate to the nature and size of the installation and shall include:**

[…]

(a) informing third parties accessing the installation to load, unload or otherwise handle pellets about the relevant procedures to prevent, contain and clean up spills and losses;

(b) at high-risk spill locations, ensuring that there are regular inspections, cleaning and maintenance of catchment devices and storage facilities as well as of packaging and containers; if leaking or sifting, packaging and containers shall not be used further;

(c) containing spills and cleaning them up as soon as possible, and at the latest at the end of the operation;

(d) the outside of the road vehicle, rail wagon or inland waterway vessels ship is free from plastic pellets when leaving the installation; and loading and unloading ramps of road vehicles and rail wagons are closed when leaving the loading or unloading place;

PUBLIC

(8a) **where appropriate on the basis of** the nature and size of the installation as well as the scale of its operations**, economic operators shall consider at least the following additional procedures:**

(a) for prevention: limits on the **[…] quantities** of pellets transported in certain packaging **[…]**; use of spill trays under transfer points and during loading and unloading; clear protocols for opening, loading, closing and sealing containers at the start and end of loading; physical testing and monitoring of the effectiveness of prevention procedures; **reception and departure procedure for EU carriers and non-EU carriers; plastic pellet dust prevention procedures and measures;**

(b) for containment: **[…]**regular inspection, cleaning and maintenance of drain covers, storm water drainage or filtration systems; regular inspection and cleaning of vehicles leaving and/or entering a site, outgoing water facilities and fences on the perimeter of the facility that are in public areas when applicable; immediate replacement or repair of leaking packaging **[…] or containers […]**; maintenance of sewage treatment system**;**

(c) for clean-up: **once the** spilled **[…]** pellets **[…] have been** cleaned up **[…], i**f possible, **[…] they** are reused as raw material to reduce wastage. If spilled plastic pellets cannot be reused as raw materials, they are retrieved and disposed of in accordance with waste legislation~~.~~**;**

(9) in addition to elements described in points (1) to (8), economic operators that are medium or large-sized enterprises and operate installations where plastic pellets in quantities **equal to or** above **a threshold of** 1 000 tonnes have been handled in the previous calendar year shall also take the following actions:

(a) describe the elements that should be reviewed at formal management meetings at least once a year including the estimated quantity and causes of any losses; preventive, mitigating and clean up equipment and procedures implemented and their effectiveness**;**

PUBLIC

(b) establish an awareness and training programme, based on the employees' specific roles and responsibilities, on prevention, containment and clean-up, the installation, use and maintenance of equipment, the execution procedures, as well as the monitoring and reporting of pellet losses;

(c) set the procedures for informing drivers, suppliers and subcontractors about the relevant procedures to prevent, contain and clean up spills and losses.

PUBLIC

ANNEX II

FORM FOR SELF-DECLARATION OF CONFORMITY

.... (name and address of the economic operator).

Declares under its sole responsibility that the handling of plastic pellets in the installation located in ..... (address) with registration number (if available) ……. meet all requirements of Regulation (EU) No […] of the European Parliament and of the Council of […] on preventing plastic pellets losses to reduce microplastic pollution.

By signing this declaration, I declare that the risk assessment attached, carried out on the …….. (date) has been implemented.

Done at … on …/…/20….

Signature

PUBLIC

ANNEX III

ACTIONS FOR EU CARRIERS AND NON-EU CARRIERS

Measures to be taken and equipment to be put in place by EU carriers and non-EU carriers:

(1) For prevention: verification during and after loading and unloading, that pellets are properly removed from the outside of the transport equipment before leaving the loading/unloading site; clear communication on stowage requirements; prevention of any leakage **[…]**during the transport journey, e.g., by technical suitability of the transport means and containers, supplemented, if necessary, with appropriate sealing; ensuring that protective covers on e.g. forklifts/hydraulic equipment are used to prevent the piercing of packaging; regularly cleaning the loading compartments and the containers to minimise the loss of spilled pellets; visual checking of openings and integrity of the loading compartments prior and, to the extent possible, during the journey, including in the multimodal terminals, rail terminals, inland and seaports**, checking the integrity of the packaging of plastic pellets. When loading and unloading operations take place, it shall be ensured that (i) the outside of the road vehicle, rail wagon or inland waterway vessels ship is free from plastic pellets when leaving the installation, and (ii) loading and unloading ramps of road vehicles and rail wagons are closed when leaving the loading/unloading place.**

(2) For containment and clean-up: where possible, repair damaged packaging **[…] during transport** and contain the remaining pellets in the loading compartment; collect the spilled pellets in closed containers or bags for proper disposal; in case of transport of pellets in bulk tanks, opening the bottom manhole/cone of the silo tank only after entering the cleaning bay; replace the container liner only in suitable and non-public areas, where any spillage can be contained; notify the authorities such as international and national emergency, or environmental authorities, as appropriate, from the Member State where the event occurred.

(3) Equipment on board: at least one portable lightening apparatus, hand tools (e.g. brooms, dustpan and brush, buckets, repair tapes, etc.); closed collection containers/reinforced collection bags.

PUBLIC

ANNEX IV

FORM OF THE CERTIFICATE OF CONFORMITY

PUBLIC

.... (name).

with registration number .....

accredited for the scope . . . . . .
. . . . . (NACE Code)

declares, after having verified the installation of the economic operator …… (name) located in …….. with registration number (if available)
.....

that the installation meets all requirements laid down in Annex I of Regulation (EU) No […] of the European Parliament and of the Council of […] on preventing plastic pellets losses to reduce microplastic pollution.

By signing this declaration, I declare that:

— the verification has been carried out in full compliance with the requirements of Regulation (EU) No […], including spot-checks performed in …….. (dates),

— the outcome of the verification confirms that there is no evidence of non-compliance with the applicable legal requirements of Regulation (EU) No […].

Done at … on …/…/20….

Signature **and stamp**